SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Benylin Chesty Coughs (Original)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:-

Diphenhydramine hydrochloride 14.0 mg
L-menthol 2.0 mg

3 PHARMACEUTICAL FORM

Syrup.
A clear red syrup

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
BENYLIN CHESTY COUGHS (ORIGINAL) is indicated for the relief of
cough and associated congestive symptoms.

4.2 Posology and method of administration

For oral use

Adults and Children aged 12 years and over:

One 10 ml dose of syrup 4 times a day.
Maximum daily dose: 40 ml syrup.

Children under 12 years:

Benylin Chesty Coughs (Original) is contraindicated in children under the age
of 12 years (see section 4.3).
The Elderly:

As for adults above (see Pharmacokinetics - The elderly).

Hepatic dysfunction
Caution should be exercised if moderate to severe hepatic dysfunction is present (see Pharmacokinetics - Hepatic dysfunction).

Renal dysfunction
It may be prudent to increase the dosage interval in subjects with moderate to severe renal failure (see Pharmacokinetics - Renal dysfunction).

Do not exceed the stated dose.

Keep out of the reach and sight of children.

4.3 Contraindications

BENYLIN CHESTY COUGHS (ORIGINAL) is contraindicated in individuals with known hypersensitivity to the product or any of its constituents.

Benylin Chesty Coughs (Original) is contraindicated in individuals with chronic or persistent cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by the physician.

Benylin Chesty Coughs (Original) should not be administered to patients currently receiving monoamine oxidase inhibitors (MAOI) or those patients who have received treatment with MAOIs within the last two weeks.

Not to be used in children under the age of 12 years.

4.4 Special Warnings and Precautions for Use

This product may cause drowsiness. If affected individuals should not drive or operate machinery.

Subjects with moderate to severe renal or hepatic dysfunction or urinary retention should exercise caution when using this product (see Pharmacokinetics - Renal/Hepatic Dysfunction).

This product contains diphenhydramine and therefore should not be taken by individuals with narrow-angle glaucoma or symptomatic prostatic hypertrophy.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5. Interactions with other medicinal products and other forms of interaction

This product contains diphenhydramine and therefore may potentiate the effects of alcohol, codeine, antihistamines and other CNS depressants.

As diphenhydramine possesses some anticholinergic activity, the effects of anticholinergics (eg, some psychotropic drugs and atropine) may be potentiated by this product. This may result in tachycardia, dry mouth, gastrointestinal disturbances (eg, colic), urinary retention and headache.

4.6. Pregnancy and Lactation

Although diphenhydramine has been in widespread use for many years without ill consequence, it is known to cross the placenta and has been detected in breast milk. BENYLIN CHESTY COUGHS (ORIGINAL) should therefore only be used when the potential benefit of treatment to the mother exceeds any possible hazards to the developing foetus or suckling infant.

4.7. Effects on Ability to Drive and Use Machines

This product may cause drowsiness. If affected, the patient should not drive or operate machinery.

4.8. Undesirable Effects

Side effects associated with the use of BENYLIN CHESTY COUGHS (ORIGINAL) are uncommon.

Diphenhydramine may cause: drowsiness; dizziness; gastrointestinal disturbance; dry mouth; nose and throat; difficulty in urination or blurred vision.

Less frequently it may cause palpitations, tremor, convulsions or parasthesia.

Hypersensitivity reactions have been reported, in particular, skin rashes, erythema, urticaria and angiodema.

Adverse reactions to menthol at the low concentration present in BENYLIN CHESTY COUGHS (ORIGINAL) are not anticipated.
4.9. **Overdose**

**Symptoms and signs**

The symptoms and signs of BENYLIN CHESTY COUGHS (ORIGINAL) overdose may include drowsiness, hyperpyrexia and anticholinergic effects. With higher doses, and particularly in children, symptoms of CNS excitation including hallucinations and convulsions may appear; with massive doses, coma or cardiovascular collapse may follow.

**Treatment**

Treatment of overdose should be symptomatic and supportive. Measures to promote rapid gastric emptying (with Syrup of Ipecac-induced emesis or gastric lavage) and, in cases of acute poisoning, the use of activated charcoal may be useful. Seizures may be controlled with Diazepam or Thiopental Sodium. The intravenous use of Physostigmine may be efficacious in antagonising severe anticholinergic symptoms.

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**5 PHARMACOLOGICAL PROPERTIES**

5.1 **Pharmacodynamic properties**

Diphenhydramine possesses antitussive, antihistaminic and anticholinergic properties. Experiments have shown that the antitussive effect (resulting from an action on the brainstem) is discrete from its antihistaminic effect. The duration of activity of diphenhydramine is between 4 and 8 hours. Menthol has mild local anaesthetic and decongestant properties.

5.2. **Pharmacokinetic Properties**

**Absorption**

Diphenhydramine and menthol are well absorbed from the gut following oral administration. Peak serum levels of diphenhydramine following a 50 mg oral dose are reached at between 2 and 2.5 hours.

**Distribution**

Diphenhydramine is widely distributed throughout the body, including the CNS. Following a 50 mg oral dose of diphenhydramine, the volume of distribution is in the range 3.3 - 6.8 l/kg, and it is some 78% bound to plasma proteins.
Metabolism and Elimination

Diphenhydramine undergoes extensive first pass metabolism. Two successive N-demethylations occur, with the resultant amine being oxidised to a carboxylic acid. Values for plasma clearance of a 50 mg oral dose of diphenhydramine lie in the range 600-1300 ml/min and the terminal elimination half-life lies in the range 3.4 - 9.3 hours. Little unchanged drug is excreted in the urine. Menthol is hydroxylated in the liver by microsomal enzymes to p-methane-3,8 diol. This is then conjugated with glucuronide and excreted both in urine and bile as the Glucuronide.

The Elderly

Pharmacokinetic studies indicate no major differences in distribution or elimination of Diphenhydramine compared to younger adults.

Renal Dysfunction

The results of a review on the use of Diphenhydramine in renal failure suggest that in moderate to severe renal failure, the dose interval should be extended by a period dependent on Glomerular filtration rate (GFR).

Hepatic Dysfunction

After intravenous administration of 0.8 mg/kg Diphenhydramine, a prolonged half-life was noted in patients with chronic liver disease which correlated with the severity of the disease. However, the mean plasma clearance and apparent volume of distribution were not significantly affected.

5.3. Preclinical Safety Data

Mutagenicity
The results of a range of tests suggest that neither diphenhydramine or menthol have mutagenic potential.

Carcinogenicity
There is insufficient information to determine the carcinogenic potential of diphenhydramine or menthol, although such effects have not been associated with these drugs in animal studies.

Teratogenicity
The results of a number of studies suggest that the administration of either diphenhydramine or menthol does not produce any statistically significant teratogenic effects in rats, rabbits and mice.

Fertility
There is insufficient information to determine whether diphenhydramine has the potential to impair fertility, although a diminished fertility rate has been observed in mice in one study.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

- Ammonium chloride
- Liquid Glucose
- Sucrose
- Ethanol 96%
- Glycerol
- Sodium citrate
- Saccharin sodium
- Citric acid monohydrate
- Sodium benzoate
- Caramel T12
- Raspberry flavour 503.850/T
- Carbomer
- Ponceau 4R (E124)
- Purified water

6.2. Incompatibilities

None known

6.3. Shelf life

2 years

6.4. Special Precautions for Storage

Do not store above 25°C

6.5. Nature and contents of container

125, 150 or 300ml amber glass bottles with a 2 piece or a 3 piece plastic child resistant, tamper evident closure fitted with a polyterephtalate ethylene faced aluminium/expanded polyethylene laminated wad
6.6. **Instructions for Use, Handling and Disposal**

None applicable

7. **MARKETING AUTHORISATION HOLDER**

McNeil Products Limited
Foundation Park
Roxborough Way
Maidenhead
Berkshire SL6 3UG
United Kingdom

8. **MARKETING AUTHORISATION NUMBER(S)**

PL 15513/0048

9. **DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION**

21/03/2006

10. **DATE OF REVISION OF THE TEXT**

30/07/2014